

REMARKS

Claims 1-19 were previously pending in this application. Claims 2-17 and 19 have been canceled. Claims 1 and 18 have been amended to overcome the double patenting rejection and to correct a typographical error. New claims 20-41 have been added. Support for the amendments and for the new claims can be found in the specification, for example, on page 8, line 11, on page 58, lines 17-18, and on page 62, line 10 – page 68, line 19. As a result, claims 1, 18, and 20-41 are currently pending for examination with claims 1 and 18 being independent claims. No new matter has been added.

Information Disclosure Statement

The Examiner objected to the information disclosure statement filed 14 July 2003 for failing to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document, each non-patent literature publication or that portion which caused it to be listed, and all other information or that portion which caused it to be listed. The Examiner indicated that the information disclosure statement has been placed in the application file, but the information referred to therein have not been considered. The Examiner is requesting that the Applicant inform the Examiner that if the Applicant has submitted these references in a prior application where the cited foreign patent documents and non-patent literature can be found.

The aforementioned cited foreign patent documents and non-patent literature have been submitted previously with application 09/846,838. Applicant had previously indicated to the Examiner (on page 7 of Form 1449 that was filed with the information disclosure statement on July 14, 2003) that the cited documents were submitted previously with application 09/846,838. The Examiner is kindly requested to consider the aforementioned prior art documents and provide the applicant with a signed copy of the information disclosure statement with the next action.

Claim Objections

Claims 1 and 18 have been objected to because the word *cis*-docosahexanoic acid was misspelled. The typographical error has been corrected. Withdrawal of the claim objection is kindly requested.

Claim Rejections - 35 USC § 112

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 19 has been canceled. Accordingly withdrawal of the rejection under §112 is kindly requested.

Claim Rejections - 35 USC § 103

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al (U.S. Pat. No. 5,925,669 A). The Examiner asserts that Katz et al. “teach the use of pharmaceutical compositions containing DHA as a carrier for anti-neoplastic drugs (column 6, lines 20-25) for the treatment of lung cancer, breast cancer, colon cancer, prostatic carcinoma, leukemia and brain cancers (column 6, lines 43-52).” According to the Examiner, it would have been made obvious to one of ordinary skill in art at the time it was made to employ cis-docosahexaenoic acid conjugates as carriers for anti-neoplastic agents motivated by the teaching of Katz et al. who teaches that these docosahexaenoyl type fatty acids are desirable as carriers for anti-neoplastic agents to inhibit the proliferation of malignant cells, control the growth of malignant neoplasms, prolong remission time and the survival time of a mammal, kill malignant cells and adversely affect malignant cells (column 6, lines 9-19).”

Claims 1 and 18 have been amended and claims 2-17 and 19 have been canceled. As currently amended, the claims are directed to methods for targeting a drug to a non-central nervous system tissue (to treat a non-central nervous system condition) and to pharmaceutical preparations comprising a *covalent* conjugate of cis-docosahexaenoic acid and a noncentral nervous system active agent wherein the noncentral nervous system active agent is a Vitamin D analog (calcitriol, 22-oxacalcitriol, fluocalcitriol, calcipotriol, calcipotriene, calcifediol, secalciferol, dihydrotachysterol, 20-epi-1,25 dihydroxyvitamin D3, 1 alpha-hydroxyvitamin D2, or alfacalcidol).

The teachings of Katz et al. are limited to pharmaceutical compositions containing DHA as a carrier for anti-neoplastic drugs and to the use of such pharmaceutical compositions for the treatment of cancer. Katz et al. does not teach or suggest pharmaceutical compositions of drugs other than anti-neoplastic drugs or the use of such compositions for the treatment of conditions other than cancer. Katz et al. does not teach or suggest pharmaceutical compositions of Vitamin D analogs. Moreover, Katz et al. teaches pharmaceutical compositions containing DHA as a

carrier for anti-neoplastic drugs i.e., pharmaceutical compositions in which the anti-neoplastic drug is dispersed in the oil (Katz et al. column 7, lines 49-52). Katz et al. does not teach or suggest *covalent conjugates* of DHA and drugs as taught by the instant invention.

The teachings of Katz et al. do not provide the suggestion or the motivation to one of ordinary skill in the art to employ pharmaceutical compositions comprising DHA and Vitamin D analogs let alone *covalent conjugates* of DHA and a Vitamin D analog as claimed in the instant invention. Thus, the instant invention is not obvious in view of the teachings of Katz et al. Accordingly, withdrawal of the rejection under § 103 is kindly requested.

Statutory Double Patenting

Claims 1-4, 6 18 and 19 have been rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6, 7 and 8 of prior U.S. Patent No. 6,602,902 B2. Independent claims 1 and 18 have been amended. Claims 2-17 and 19 have been canceled. As currently amended, the instant claims no longer claim the same invention as claims 1-4, 6, 18 and 19 of U.S. Patent No. 6,602,902 B2. Accordingly, withdrawal of the statutory double patenting rejection is kindly requested.

Non-Statutory Double Patenting

Claims 1-17 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-12 of U.S. Patent No. 5,795,909 ("the '909 Patent"). Claims 18 and 19 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10 of U.S. Patent No. 6,080,877 ("the '877 Patent") and claims 1-10 of U.S. Patent No. 5,919,815 ("the '815 Patent").

Without conceding the correctness of the Examiner's position, Applicant has filed herewith a terminal disclaimer to the '909 Patent, the 877 Patent and the '815 Patent. Accordingly, withdrawal of the obviousness-type double-patenting rejection over these three patents is kindly requested.

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CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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